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#33

Lisa B. Kole  
Baker & Botts LLP  
30 Rockefeller Plaza  
New York NY 10112

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,784,950

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,784,950, which claims the drug product NOVOSEVEN® (rhFVIIa) and methods of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension, if calculated using the Food and Drug Administrations determination of the length of the regulatory review period published in the Federal Register of 68 Fed. Reg. 3534, pursuant to 35 U.S.C. § 156(c), would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,904 - 171) + 1,050 \\ &= 2,417 \text{ days (6.6 years)}\end{aligned}$$

Since the regulatory review period began May 29, 1988, before the patent issue date (November 15, 1988), the period from May 29, 1988 until and including November 15, 1988 has not been included in the above determination. (See 35 U.S.C. 156(c)(“the regulatory review period...which occurs after the date the patent issued.”) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitation of 35 U.S.C. § 156(g)(6)(A), however, operates to reduce the period of extension determined above to a period of five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not further limit the term of the extension in the present situation. (The approval date was March 25, 1999, thus the 14 year limit would be March 25, 2013. Since March 25, 2013 is after November 15, 2010, the 14-year limit does not apply.)

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,784,950

Granted: November 15, 1988

Applicant: Hagen et al.

Owner of Record: ZymoGenetics, Inc.

Title: Expression of Factor VII Activity in Mammalian Cells

Classification: 435/068

Product Trade Name: NOVOSEVEN® (rhFVIIa)

Term Extended: Five Years

Extended Expiration Date November 15, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Box Patent Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Ferriter

Karin L. Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane,  
Rockville, MD 20857

FDA Docket No.:NOVOSEVEN® (rhFVIIa)  
RE: 99E-5112

Attention: Claudia Grillo